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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/516,944

12/16/2004

Takashi Narui

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11/26/2008

OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

MERCIER, MELISSA S

ART UNIT

PAPER NUMBER

1615

NOTIFICATION DATE

DELIVERY MODE

11/26/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/516,944	Applicant(s) NARUI ET AL.	
	Examiner MELISSA S. MERCIER	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12-16-04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Receipt of the Preliminary Amendment filed on December 16, 2004 is acknowledged. Claims 1-9 are pending in this application.

Priority

Applicants Claim of Priority to PCT/JP03/08400 filed on July 2, 2003 and Japanese Application 2002-206565 filed on July 16, 2002 is acknowledged. Receipt of the certified foreign priority documents is also acknowledged.

Information Disclosure Statement

Receipt of the Information Disclosure Statement filed on December 16, 2004 is acknowledged.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which

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was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite a transdermal absorption promotion composition comprisinga lauromacrogol. A review of the specification applicant's definition of a lauromacrogol as a compound with excellent mutual solubility with propylene glycol. Although not specifically limited, lauryl ethers with 2-25 mol, preferably 2-9 mol ethylene oxide addition are preferable (Specification, page 4, lines 16-19). This definition and one example do not provide adequate written description for the entire genus of lauromacrogols in the instant claims, which according to answers.com include one of the anti itch ingredients, which rapidly relieves the itching caused by dry skin conditions such as eczema.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5 and 7-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 5, it is unclear what "comparatively high lipophilic properties" are. It is unclear what kind of comparison applicant is referring to and what actual drugs are being compared. The examiner has interpreted the limitation to be a lipophilic drug component.

Claims 7-8 recites the limitation "components a-d" in line 2. There is insufficient antecedent basis for this limitation in the claim. The claims are presented as independent claims. Therefore, it is unclear what components applicant is referring to. For purposes of prosecution, the examiner has interpreted the components to be those recited in claim 4; however, appropriate correction is needed in order to clarify the claim limitations.

Further regarding claim 7, it is unclear what Applicant is claiming by "basically comprising". The Examiner has interpreted the claim language to "comprise".

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ikeda et al (US Patent 6,207,184).

The claims are drawn to a transdermal absorption promotion composition comprising 3 permeation enhancers (components A-C). Additional independent claims further incorporate a drug substance (component D). . Specific percentages of the enhancers are claimed.

Ikeda discloses hydrophilic adhesive masses incorporating a pharmaceutical active (abstract). Polymer solubilizers, including propylene glycol, propylene glycol monocaprylate (polyol fatty acid ester), and polyoxyethylene lauryl ether (lauromacrogol) are disclosed. They can be used in the proportion of 0.5-70 wt. (column 3, lines 16-40).

Regarding claim 2, since the prior art discloses Applicants preferred components A-C; it is the position of the examiner that it would meet the limitations of the instant claim.

Regarding claim 3, Applicant is reminded that where the general conditions of the claims are met, burden is shifted to applicant to provide a patentable distinction. Where

the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See *In re Aller*, 220 F.2d 454, 105 USPQ 233,235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the permeation enhancers). However, the preparation of various sanitizing compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. See *In re Russell*, 439 F.2d 1228, 169 USPQ 426 (CCPA 1971).

Regarding claim 5, Ikeda discloses numerous salicylate derivatives (column 4, lines 25-28), which are known to be lipophilic.

Regarding claim 6, the adhesive mass can be used in a hydrophilic plaster (abstract).

It has been held that combinations of two or more compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is to be used for the very same purpose. *In re Susi*, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (1960). As the court explained in *Crockett*, the idea of combining them flows logically from their having been individually taught in prior art. Therefore, since each of the references teach that propylene glycol, a polyol fatty acid ester, and a lauromacrogol, it would have been obvious to combine the permeation enhancers with the expectation that such a

combination would be effective in skin care compositions. Thus, combining them flows logically from their having been individually taught in prior art.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over El Khoury (US Patent 5,994,330).

El Khoury discloses topical applications comprising muscarinic agents, such as neostigmine (column 1, lines 7-13). Suitable topical transdermal enhancing agents include propylene glycol, sefsol (a polyol fatty acid ester) and Brij (polyoxyethylene lauryl ether; a lauromacrogol) (column 15, lines 3-30). It is additionally disclosed combination of enhancers can lead to synergistic actions, and the determination of suitable transdermal enhancing preparations for a given use is routine in the art.

Regarding claim 2, since the prior art discloses Applicants preferred components A-C; it is the position of the examiner that it would meet the limitations of the instant claim.

Regarding claim 3, Applicant is reminded that where the general conditions of the claims are met, burden is shifted to applicant to provide a patentable distinction. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See *In re Aller*, 220 F.2d 454, 105 USPQ 233,235 (CCPA 1955).

Furthermore the claims differ from the reference by reciting various concentrations of the permeation enhancers). However, the preparation of various sanitizing compositions having various amounts of the active is within the level of skill of

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one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. See *In re Russell*, 439 F.2d 1228 169 USPQ 426(CCPA 1971).

Regarding claim 6, the formulation may be in the form of a gel, cream, spray, lotion, or spray (abstract).

Regarding claims 7-8, numerous carriers, including petrolatum and lanolin, as well as water in oil emulsions are disclosed (column 13, lines 52-67).

It has been held that combinations of two or more compositions each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is to be used for the very same purpose. *In re Susi*, 58 CCPA 1074, 1079-80, 440 F.2d 442, 445, 169 USPQ 423, 426 (1971); *In re Crockett*, 47 CCPA 1018, 1020-21, 279 F.2d 274, 276-77, 126 USPQ 186, 188 (1960). As the court explained in *Crockett*, the idea of combining them flows logically from their having been individually taught in prior art. Therefore, since each of the references teach that propylene glycol, a polyol fatty acid ester, and a lauromacrogol, it would have been obvious to combine the permeation enhancers with the expectation that such a combination would be effective in skin care compositions. Thus, combining them flows logically from their having been individually taught in prior art.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa S. Mercier whose telephone number is (571) 272-9039. The examiner can normally be reached on 7:30am-4pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melissa S Mercier/
Examiner, Art Unit 1615

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615